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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,163	03/26/2004	David S. F. Young	2056.029	8351

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EXAMINER	
UNGAR, SUSAN NMN	
ART UNIT	PAPER NUMBER
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,163	YOUNG ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *26 March 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Claims 32 are pending in the application and are currently under prosecution.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1. Claims 1-8 are drawn to a method of extending survival and/or delaying disease progression of a human tumor in a mammal by administering antibody with identifying characteristics of PTA 5691, classified in Class 424, subclass 130.1.

Group 2. Claims 9-16 are drawn to monoclonal antibody PTA5691 and the clone deposited as PTA-5691, classified in Class 435, subclass 326, class 530, subclass 387.1.

Group 3. Claims 17-20 are drawn to a method of screening/detecting the presence of cancerous cells in a tissue sample from a human tumor with antibody PTA5691, classified in Class 435, subclass 7.1.

Group 4. Claims 21-28 are drawn to antibody PTA-5690 and the clone deposited as PTA-5690, classified in Class 435, subclass 326, class 530, subclass 387.1.

Group 5. Claims 29-32 are drawn to a method of screening/detecting the presence of cancerous cells in a tissue sample from a human tumor with antibody PTA5690, classified in Class 435, subclass 7.1.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions 2 and 4 as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions. For Example, antibody 5691 binds to antigens found

in breast and ovarian cancers while antibody 5690 binds to antigens found in colon cancer. The antigens are used for diagnosis of different types of cancers. Further, the antibodies are unrelated in structure because the binding parameters/structure necessary for binding to different antigens are different. The exquisite sensitivity of antibodies for binding to their own particular epitope is made possible by the wide variety of structures in the variable domains of antibodies. Given the differences in the two antibodies, the two claimed antibodies are distinct and searching for both of these antibodies would be an undue burden on the Examiner.

Inventions 1, 3, 5 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. The method of claim 1 is drawn to the *in vivo* treatment of cancer requiring different method steps, schedules, dosages from the methods of claims 3 and 5 which are *in vitro* binding assays. Clearly, the objectives of *in vitro* binding assays are different from *in vivo* treatment, Further, as drawn to the binding assays, the assays are distinct because they are done in different tissue types wherein different antigens are identified. Given these differences, the three methods are distinct and searching each of these methods would be an undue burden on the Examiner.

The inventions of Groups 2 and 1/3 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* **806.05(h)**]. In the instant case the antibody product as claimed can be used in a materially different process such as production of anti-idiotypic antibodies.

The inventions of Groups 4 and 5 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP*. **806.05(h)**]. In the instant case the antibody product as claimed can be used in a materially different process such as production of anti-idiotypic antibodies.

The inventions of Groups 2 and 5 are not at all related because the invention of group 2 is not used in any of the methods of Group 5.

The inventions of Groups 4 and 1/3 are not at all related because the invention of group 4 is not used in any of the methods of Group 1/3.

The inventions of Groups 5 and 3/7 are not at all related because the invention of Groups 3/7 are not used in any of the methods of Group 5.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Group 1 is further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising antibodies wherein said antibodies have different structures and functions wherein said antibodies (a) are conjugated to cytotoxic moieties (claims 2 and 3), (b) activate complement (claim 4), (c) mediate ADCC (claim 5).

6. Group 1 is further subject to election of a single disclosed species comprising antibody conjugates wherein the conjugated moieties have different structures and functions wherein the moieties are (a) cytotoxic moieties, (b)

enzymes, (c) radioactive compounds (d) hematogenous cells, as contemplated in the specification.

7. Group 2 is further subject to election of a single disclosed species comprising antibody conjugates wherein the conjugated moieties have different structures and functions wherein the moieties are (a) cytotoxic moieties, (b) enzymes, (c) radioactive compounds (d) hematogenous cells, all of claim 15.

8. Group 4 is further subject to election of a single disclosed species comprising antibody conjugates wherein the conjugated moieties have different structures and functions wherein the moieties are (a) cytotoxic moieties, (b) enzymes, (c) radioactive compounds (d) hematogenous cells, all of claim 27.

9. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

10. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

11. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by

37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP. 809.02(a).

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

14. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

15. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend**

from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone

number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at 571-272-0898. The fax phone number for this Art Unit is (571) 273-8300.

Susan Ungar, PhD
Primary Patent Examiner
December 20, 2006